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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/229,229	01/12/1999	GEOFFREY M. WAHL		7340

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/229,229	WAHL ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-38,40-49 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-38, 40-49 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed May 6, 2004 is acknowledged.

2. Claims 5-27, 31, 32, 39, 50-52 and 54 were canceled. Claims 33-38, 40-49 and 53 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained and New Grounds of Rejection:

4. The rejection of claims 33-38, 40-49 and 53 under 35 U.S.C. 103(a) as being unpatentable over Robinett (Journal of Cell Biology (1996) 135(6): 1685-1700) in view of Abken (Cancer Journal (1995) 8(3): 94-102) is maintained. The rejection is maintained because the claims contain the phrase "or analog thereof", which broadens the scope so that the claims read on almost any protein that associates with double minute chromosomes or extrachromosomal DNA. Because this rejection was not applied to the now canceled dependent claims, this rejection constitutes a new grounds of rejection.

Robinett teaches a method for visualizing chromosomes in Chinese Hamster Ovary (CHO) cells by transfecting cells with an expression vector containing DNA encoding a GFP-lac repressor-nuclear localization signal fusion protein (page 1687). A GFP-lac repressor-nuclear

localization signal fusion protein is a labeled protein that associates with double minute chromosomes or extrachromosomal DNA.

Abken teaches that extrachromosomal DNA and double minute DNA is chromosomal in origin and that double minute DNA can be eliminated from cancer cells by micronuclei formation in response to administration of various drugs. Abken also teaches that extrachromosomal DNA such as double minute DNA contains extra copies of oncogenes, which may cause the growth dysregulation of cancer cells. Abken also teaches that extrachromosomal DNA such as double minute DNA contains extra copies of oncogenes, which may cause the growth dysregulation of cancer cells. Furthermore, Abken teaches an examples of agents that induces micronuclei formation and the reduction of double minute chromosomes (DM), hydroxyurea, inhibitors of poly(ADP-ribose) polymerase, and dimethyl sulfoxide, and suggests that analyses of the stability of extrachomosomal DNA molecules provides a rational basis for design of innovative therapeutic strategies (see page 99, 1st col.). Thus, Abken provides the teachings that suggest methods for screening for such agents because Abken teaches that such agents have already been discovered and that such agents result in differentiation of tumor cells, and that such agents may be the basis for a therapeutic strategies.

The motivation to combine the teachings of Robinett with Abken is that Robinett teaches methods for visualizing chromosomes, and therefore provides a method for visualizing extrachromosomal DNA or double minute DNA, which methods could be used in methods to determine if an agent were increasing or decreasing the amount of extrachromosomal DNA or double minute DNA.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to use the technique of chromosome visualization taught by Robinett to make a method for identifying other agents that induce micronuclei formation and thereby decrease the amount of double minute chromosomes. Alternatively, because the presence of double minutes is associated with carcinogenesis, it would be prima facie obvious to use the technique of Robinett to identify agents that increase the amount of double minute DNA or extrachromasomal DNA.

5. Claims 33-38, 40-49 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the description in the specification of histone proteins that may be useful in the claimed methods (H2B, H3, H4, H2A or H2B) is not representative of the genus of "histone analogues". Therefore, the genus of histone analogs is not adequately described such that one of skill in the art would understand that applicant was in possession of the claimed methods, because the claimed methods read on methods using histone analogs.

Applicants' arguments have been carefully considered, but fail to persuade. Applicant has not pointed to a definition in the specification of what protein is considered to be a "histone analog" and which is not. Absent a definition of the structure, the functional language provided in the claims is used as a basis for a broadest reasonable interpretation. The broadest reasonable interpretation of the claimed inventions, is that the claims are drawn to methods comprising the

use of cells containing a labeled protein that associates with double minute chromosomes or extrachromosomal DNA to form a labeled complex. Applicant appears to be arguing that a structure of any "histone analog" would be known by one of skill in the art.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is for purposes of the 'written description' inquiry, "*whatever is now claimed*" (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed by "histone analogs" used in the method claims and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of manufacturing or testing the claimed process. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or testing it. One cannot describe what one has not conceived. See Fides v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112, is severable from its enablement provision. (See page 1115).

Conclusion

No claim is allowed. Claims 33-38, 40-49 and 53 are rejected.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
August 9, 2004